EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-158

LG Life Sciences, Ltd
C/o PAREXEL International
Attention: Gail Glifort
2520 Meridian Parkway, Suite 200
Durham, North Carolina 27713

Dear Ms. Glifort:

Please refer to your new drug application (NDA) dated December 15, 1999, received December 16, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Factive (gemifloxacin mesylate) Tablets, 320 mg.

We acknowledge receipt of your submissions dated as follows:

October 14, 2002	December 16, 2002	February 12, 2003
October 24, 2002	December 20, 2002	February 17, 2003
October 29, 2002	December 30, 2002 (2)	February 18, 2003
October 30, 2002	January 2, 2003	February 20, 2003
October 31, 2002	January 9, 2003	February 21, 2003
November 1, 2002	January 10, 2003	February 27, 2003 (2)
November 4, 2002	January 16, 2003	March 24, 2003
November 14, 2002	January 22, 2003	March 27, 2003
November 25, 2002	January 24, 2003	March 28, 2003 (2)
November 26, 2002	January 30, 2003	April 4, 2003
December 9, 2002 (3)	January 31, 2003	
December 12, 2002	February 11, 2003	

Your October 4, 2002 submission constituted a complete response to our December 15, 2000 action letter.

This new drug application provides for the use of Factive (gemifloxacin mesylate) Tablets for the treatment of community-acquired pneumonia and acute bacterial exacerbation of chronic bronchitis.

We have completed the review of this application, as amended. We have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved for these indications, effective on the date of the letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted April 3, 2003) and the agreed-upon labeling (immediate container and carton labels submitted March 28, 2003 to be amended as agreed during our April 2, 2003 teleconference and as stated in your April 3, 2003 submission). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the

FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission **FPL for approved NDA 21-158.**? Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submission dated March 28, 2003:

1. Comparative Safety Study

   Conduct a prospective, randomized study comparing gemifloxacin (5,000 patients) to an active control (2,500 patients) in patients with community-acquired pneumonia (CAP) or acute bacterial exacerbation of chronic bronchitis (ABECB). At least 10% of patients should be of African origin, 10% of Asian origin and 10% of Hispanic origin to gain safety information in other minority or ethnic groups, specifically as it relates to rash. Patients should be evaluated for clinical and laboratory safety.

Protocol Submission:	Within 3 months of the date of this letter
Study Start:	Within 11 months of the date of this letter
Interim Report Submission:	Within 12 months of date of this letter (with the annual report)
Final Report Submission:	Within 4 years of the initiation of the study

2. Prescribing Patterns and Use

   Conduct a study to evaluate the prescribing patterns and use of gemifloxacin. In this study, obtain data on the prescribing patterns and use of gemifloxacin for the first three years after initial marketing in the US. Include the number of prescriptions issued (as well as the rate of refills) and the diagnoses for which the prescriptions were dispensed. These data may be obtained from various databases such as HMOs, governmental agencies, and pharmacy organizations.

Protocol Submission:	Within 4 months of the date of this letter
Interim Report Submission:	Within 12 months of date of this letter (with the annual report)
Final Report Submission:	Within 5 years of date of this letter

The Division anticipates discussing the details of the above studies at your earliest convenience.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **Postmarketing Study Protocol? 밟ostmarketing Study Final Report? or 밟ostmarketing Study Correspondence.**

FDA's Pediatric Rule at 21 CFR 314.55 was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Therefore, we encourage you to submit a pediatric plan that describes development of your product in the pediatric population where it may be used. Please be aware that whether or not this pediatric plan and subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal. In

any event, we hope you will decide to submit a pediatric plan and conduct the appropriate pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products. You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request". FDA generally does not consider studies submitted to an NDA before issuance of a Written Request as responsive to the Written Request. Applicants should obtain a Written Request before submitting pediatric studies to an NDA.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Immunologic Drug products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-158 for this drug product. We also note that you agreed to evaluate spontaneously reported adverse events, particularly for the cutaneous, hepatic, musculoskeletal, and cardiac (conducting system) organ systems, annually for the first three years after initial marketing in the US.

If you have any questions, call Yon Yu, Pharm. D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Mark J. Goldberger, M.D., M.P.H.
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mark Goldberger
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